

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 287-432, 434-442, 446-493, 495-503, 506-521, 523-531, 535-539, 541-549, 553-608, 611-619, and 622 are pending in the application, with claims 287, 300, 319, 340, 351, 362, 374, 389, 404, 416, 431, 446, 459, 476, 492, 507, 518, 535, 553, 565, 580, 595 and 608 being the independent claims. Claims 300-318, 340-350, 374-388, 416-430, 459-475 and 595-607 are allowed. Claims 433, 443, 444, 445, 494, 504, 505, 522, 532, 533, 534, 540, 550, 551, 552, 609, 610, 620, and 621 are sought to be canceled without prejudice to or disclaimer of the subject matter therein. Applicants retain the right to pursue the subject matter of the canceled claims in one or more continuing applications. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Claim Objections

The Examiner has objected to claim 433 as allegedly being of improper dependent form. Paper No. 34, page 3. Solely to advance prosecution and not in acquiescence to the Examiner's objection, claim 433 has been canceled without prejudice or disclaimer. The Examiner's objection is moot and Applicants, therefore, respectfully request that the Examiner reconsider and withdraw the objection.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claim 494 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants' regard as the invention. Paper No. 34, page 3. Applicants respectfully traverse the rejection.

Solely to advance prosecution and not in acquiescence to the Examiner's objection, claim 494 has been canceled without prejudice or disclaimer. The Examiner's rejection is moot and Applicants, therefore, respectfully request that the Examiner reconsider and withdraw the rejection.

Rejections under 35 U.S.C. § 112

The Examiner has rejected claims 494, 522, 540, 609 and 610 under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled by the specification. (Paper No. 34, page 3.) Specifically, the Examiner has stated that "the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims" (*Id.* at page 4.) Applicants respectfully traverse the rejection.

Solely to advance prosecution and not in acquiescence to the Examiner's rejection, claims 433, 443, 444, 445, 494, 504, 505, 522, 532, 533, 534, 540, 550, 551, 552, 609, 610, 620, and 621 have been canceled without prejudice or disclaimer. Thus, the Examiner's rejection is rendered moot and Applicants, therefore, respectfully request that the Examiner reconsider and withdraw the rejection.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 492-495, 507-508, 518-523, 535-541 and 608-611 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,072,047 [the "'047 patent"']. (Paper No. 34, page 5.) According to the Examiner:

US Patent No. 6,072,047 receives priority back to March 12, 1997 (application number 08/815,255) for the DNA fragment encoding the TRAIL-R fragment in Figure 1 of the patent, which is the same as amino acids 336-386 of SEQ ID NO:2 of the patent. This TRAIL receptor fragment is identical to amino acids 256-306 of SEQ ID NO:2, which is encoded by nucleotides 1048-1200 of SEQ ID NO:1, of the instant application. The DNA fragment was obtained after the mature protein had been purified (EXAMPLE 1 and 2) by using degenerate oligonucleotide primers (heterologous polynucleotides) for PCR (EXAMPLE 3). As later shown in US Patent 6,072,047, the above fragment functions within a mature DR5 to induce apoptosis.

Paper No. 34, page 5.¹ Applicants respectfully traverse the rejection.

As noted by the Examiner, the priority application of the '047 patent discloses a nucleotide sequence encoding a polypeptide fragment consisting of amino acids 256 to 306 of SEQ ID NO:2. However, this fact is irrelevant because *none of the claims of the '047 patent are directed to this fragment*. As discussed in detail below, under *In re Wertheim*, 646 F.2d 527, 209 USPQ (BNA) 554 (CCPA 1981)(copy attached), the '047 patent is *not* available as prior art under 35 U.S.C. § 102(e) against the present application.

Under 35 U.S.C. section 102(e), the disclosure of a U.S. patent constitutes prior art as of its filing date. However, for a reference patent that claims the benefit of the

¹ Applicants note that the amino acid and nucleotide sequences disclosed in the March 12, 1997 priority document are not *identical* to amino acids 256-306 of SEQ ID NO:2, or nucleotides 1048-1200 of SEQ ID NO:1, of the present application, respectively, because nucleotides 145 and 149 are depicted as "n", and amino acid 48 is depicted as an "X".

filing date of an earlier application, courts have considered the conditions under which the priority date may be used as the patent's effective date under section 102(e). In particular, in *Wertheim*, the Court of Customs and Patent Appeals (CCPA) decided whether a U.S. patent was entitled to the filing date of a grandparent application for prior art purposes under section 102(e), when the patent claims recited subject matter that lacked support under 35 U.S.C. section 112 in the grandparent application. The PTO based the claim rejection on the portion of the disclosure in the patent that overlapped with the disclosures in the priority applications. In reversing the rejection, the CCPA stated,

the determinative question here is whether the invention claimed in the Pfluger [reference] patent finds a *supporting disclosure in compliance with § 112*, as required by § 120, in the 1961 Pfluger I [grandparent] application so as to entitle that invention in the Pfluger patent as "prior art," to the filing date of Pfluger I. Without such support, the invention, and its accompanying disclosure, cannot be regarded as prior art as of that filing date.

646 F.2d at 537. Thus, the *Wertheim* court articulated the principle that a U.S. patent only qualifies as prior art under section 102(e) as of the *effective* filing date of the patent's claims.

Here, under the rationale of *Wertheim*, the '047 patent is effective as a reference under section 102(e) as of the filing date of a priority application that supports the issued claims under section 112. Each of claims 1-32 of the '047 patent claim a polynucleotide which *at least* encodes amino acids 59 to 210 of SEQ ID NO:2. See, *e.g.*, the '047 patent, claim 5. Appl. No. 08/815,255, filed March 12, 1997, does not disclose a polynucleotide which encodes amino acids 59 to 210 of SEQ ID NO:2, which is a required element in every claim of the '047 patent. Therefore, Appl. No. 08/815,255 does not provide "a

supporting disclosure in compliance with §112, as required by § 120. . . . " Accordingly, without such support, the '047 patent cannot properly be used as prior art against the present application.

Based on these remarks, Applicants respectfully request that the rejection under 35 U.S.C. § 102(e) over the '047 patent be reconsidered and withdrawn.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 492-552 and 608-622 under 35 U.S.C. § 103(a) as allegedly unpatentable over the '047 patent. (Paper No. 34, page 6.) Applicants respectfully traverse the rejection.

For the reasons set forth above in regards to the rejection under 35 U.S.C. § 102(e), the '047 patent is not available as prior art against the instant application under *In re Wertheim*. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

The Examiner has also rejected claims 287-299, 319, 326-339, 351, 353-373, 389, 391-415, 431, 433-458, 476, 478-491, 553-565 and 567-594 under 35 U.S.C. § 103(a) as allegedly unpatentable over the '047 patent. (Paper No. 34, page 8.) Applicants respectfully traverse the rejection.

Again, for the reasons set forth above in regards to the rejection under 35 U.S.C. § 102(e), the '047 patent is not available as prior art against the instant application under *In re Wertheim*. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

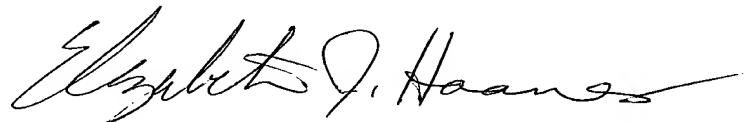
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Elizabeth J. Haanes, Ph.D.
Attorney for Applicants
Registration No. 42,613

Date: Feb. 21, 2003

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

Version with markings to show changes made

The application is sought to be amended as follows:

In the Claims:

Claims 433, 443, 444, 445, 494, 504, 505, 522, 532, 533, 534, 540, 550, 551, 552,
609, 610, 620, and 621 have been canceled.

SKGF_DC1:104332.1